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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/070,629	04/30/98	PALESE	P 6923-071-999

HM12/0913

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NEW YORK NY 10036-2711

EXAMINER

SCHEINER, L

ART UNIT	PAPER NUMBER
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1648

19

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No. 09 070, 629	Applicant(s)	
Examiner	Group Art Unit 1648	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 6/26/01.
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-5 & 20-29 is/are pending in the application.
- Of the above claim(s) 23-27 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-5, 20-22, 28 & 29 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 20-22, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record.

Claims 1-5, 20-22, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

Applicants argue that the instant specification meets the written description requirement such that the skilled would understand that applicants were in possession of the invention as claimed. Applicants contend that it is routine in the art to engineer influenza viruses and a laundry list of tumor antigens are provided by the instant specification.

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The examiner disagrees with applicants' positions since the breadth of the claimed invention is excessive and encompasses a large genus of compounds which do not receive adequate written support and are clearly not enabled. Moreover, tumor antigens aren't claimed. That is, that which is claimed must be supported by the written description. Vaccines comprising an effective amount of a recombinant tumor-associated gene containing influenza virus are claimed. The term vaccine has an art-recognized definition and pertains to the use of a compound to treat or prevent disease. Thus, the claimed compounds must provide some sort of prophylactic or therapeutic effect for patients. Applicants' response fails to provide arguments or evidence addressing this concern. Again the breadth of the claimed invention is excessive and encompasses a large genus of compounds which do not receive adequate written support and are clearly not enabled. No description of the tumor-associated gene being operably linked to a promoter has been set forth and the claims can encompass heterologous polynucleotides of varying lengths, allelic variants of any of these sequences, and sequences that have been modified to contain nucleotide additions, subtractions, and/or replacements, none of which are adequately supported by the disclosure. The claims encompass an inordinate number of species which have not been adequately described. The claimed limitations are so vague and indefinite that they fail to bear a reasonable correlation to the scope of enablement provided by the specification. That is, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. Apparently, applicants seek exclusive patent rights to all current and future vaccines comprising influenza constructs having recombinant tumor-associated antigen polynucleotide inserts. Again, applicants argue that a laundry list of tumor antigens have been provided. Applicants are reminded, however, tumor antigens are not claimed. Moreover,

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applicants fail to provide a teaching for the structure of the polynucleotides expressing the intended antigens. Regarding enablement, applicants essentially argue that their compounds and constructs are enabled since all components for making are known and have been set forth. The examiner contends that enablement is met by teaching how to make and use the claimed compounds rather than teaching the individual components employed in making the final product. Moreover, applicants have, in fact, not provided the necessary precursor components. That is, the claims are broad and the polynucleotide variants (including the influenza sequences, as well as the sequences encoding the tumor antigens) that when combined to make the final product have not been taught. Applicants' assertion that any experimentation required to practice the invention is routine is clearly incorrect since undue experimentation would be required.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

  
Laurie Scheiner/LAS  
September 9, 2001

  
LAURIE SCHEINER  
PRIMARY EXAMINER